



OPPT PFAS Activities

OCSPP AA Briefing
February 10, 2021

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Briefing Outline

- Congressional Letter: OCSPP Equities
- New Chemicals
- TSCA Section 8(a)(7) Rule
- TRI Listings
- LCPFC SNUR & Guidance



Congressional PFAS Task Force Letter: OPPT Equities

- On 1/29/21, members of Congress asked the President to take immediate steps to reduce PFAS releases, phase-out non-essential uses of PFAS in everyday products, and clean up legacy PFAS pollution. The following actions fall into OPPT's portfolio:
 - Direct EPA to ... expand reporting of these [air and water] through the Toxics Release Inventory
 - Direct the EPA to immediately place a moratorium on the introduction of new PFAS chemicals and to use all of use tools provided by the Toxic Substances Control Act to assess the risks posed by PFAS.
 - Direct EPA ... to phase out non-essential use of PFAS in ... [several FDA uses] and other household projects [read products]
 - Direct EPA ... to amend the Significant New Use Rule [read LCPFC SNUR] to address all imports.
- This briefing will summarize actions to date on TRI listings, initial considerations regarding New Chemicals actions and the PFAS SNUR promulgated in June 2020.

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The items are not listed in order of the Congressional letter; rather, in the order we will discuss to day.



PFAS: New Chemicals

- “Direct the EPA to immediately place a moratorium on the introduction of new PFAS chemicals and to use all of use tools provided by the Toxic Substances Control Act to assess the risks posed by PFAS .”

- OGC’s initial read is

Ex. 5 AC/AWP/DP

Ex. 5 AC/AWP/DP

- However, existing statutory and regulatory tools under TSCA provide EPA with several options to address the desired outcome of this Congressional directive.



New Chemicals Options to Address PFAS Moratorium

- For Low Volume Exemptions (LVEs):

Ex. 5 Deliberative Process (DP)

- For premanufacture notifications (PMNs):

Ex. 5 Deliberative Process (DP)



TSCA 8(a)(7) rule: PFAS Data Call

- 2020 National Defense Authorization Act (NDAA) added Section 8(a)(7) to TSCA
- Requires EPA to finalize a rule by January 1, 2023 requiring manufacturers (including importers) of PFAS in any year since 2011 to report certain information for each year since 2011
 - Acting AA cleared NPRM package to be sent to OMB for review
- Info collected includes chemical ID, manufactured/processed quantities, description of byproducts, worker exposure, disposal methods, existing info on environmental & health effects
- Scope of PFAS: structural definition, presented along with list of examples of substances and structural diagram examples (to capture those whose identities are CBI)



TRI PFAS Presentation Outline

- Advance Notice of Proposed Rulemaking
- National Defense Authorization Act for Fiscal Year 2020 (NDAA)
- Upcoming Actions
- Potential Future Actions
- RY 2020 PFAS Data



TRI ANPRM (published 12/4/2019)

- *Action Item in the EPA PFAS Action Plan*
- *Discussed adding certain PFAS to the TRI list and outlined:*
 - What PFAS are and why EPA was considering adding them to TRI
 - What listing actions were being considered
 - Understanding of hazard concerns & EPA's hazard assessments
 - Other information available on PFAS
- *Requested comment on:*
 - Which PFAS to list, how to list them (individually, as chemical categories, or a combination of both), appropriate reporting thresholds (considering potential persistence and bioaccumulation) and any additional data to inform evaluation and determination of which PFAS may meet the listing criteria



TRI ANPRM cont.

Received ~75 comments (about half were substantive)

- Industry comments generally:
 - Request availability of TRI reporting exemptions
 - Seek guidance on calculating estimates
 - Question inclusion of PFAS for which there is no literature regarding their toxicity
- Non-industry comments generally:
 - Want more PFAS listed & reporting thresholds below 100 pounds
- Generally, commenters prefer individual listings over categories
- No data were provided that would help list PFAS



NDAA (signed 12/20/2019)

Section 7321(b) Immediate Inclusion (effective 1/1/2020)

- Identified 14 specific PFAS to be added
- Identified additional PFAS that must be added based on
 - Whether it was on the active TSCA inventory and
 - Subject to either one of two specific TSCA Significant New Use Rules (SNURs)
- EPA determined that this section added 172 non-CBI PFAS to the TRI list
- A final rule that formally added these 172 PFAS to the CFR was published June 22, 2020



NDAAs cont.

Section 7321(c) Inclusion Following Assessment (effective January 1 of the calendar year following any action(s) below)

- EPA publishes a final toxicity value
- EPA publishes a new covered PFAS SNUR
- EPA adds a PFAS to an existing covered SNUR
- PFAS added as an active chemical substance under certain sections of TSCA

For RY 2021, three PFAS were added to the TRI list based on the above SNUR provisions



NDAA cont.

Section 7321(d) Inclusion Following Determination

- Directs EPA to evaluate:
 - 14 specifically listed PFAS
 - PFAS with an EPA approved test method for drinking water
 - PFAS used to make fluorinated polymers
- We have identified approximately 300 PFAS that require a listing determination
- EPA has 2 years from the date of the act (12/20/2019) to make a listing determination and then 2 more years to add the PFAS to the TRI list



Upcoming TRI Actions

- Final rule to include the 3 PFAS added for 2021 via section 7321(c) in the CFR
 - Discuss form of rule (final or notice & comment)
 - Recommendation: **Ex. 5 Deliberative Process (DP)**

Ex. 5 Deliberative Process (DP)

- Determine by 12/20/2021 which of **Ex. 5** PFAS identified under section 7321(d) are candidates for listing
- Certain PFAS **Ex. 5** that were identified for immediate addition under section 7321(b) were CBI and need further evaluation per section 7321(e) before they can be added (which should happen this year)



LCPFAC Significant New Use Rule (SNUR) Outline

- Background on Significant New Use Rules
- Proposed LCPFAC Rule
- Supplemental Proposal of LCPFAC Rule for Lifting Articles Exemption
- Final Rule
- Surface Coating Guidance
- Options for Guidance



Background: Existing Chemical SNURs

- EPA has authority to designate a particular new use (or return of an old use) of an existing chemical substance as a "significant new use" under TSCA section 5(a)(2).
 - **Ongoing** uses of an existing chemical are outside the scope of a SNUR, i.e., if ongoing, not a "new" use.
- Chemicals subject to existing chemical SNURs often have been manufactured (including import) for a use previously but has ceased or been phased out.
 - In developing an existing chemical SNUR, EPA researches whether uses are ongoing and includes those that data/information indicate are not ongoing.
 - Notice & comment serves to allow anyone with ongoing uses to inform EPA of such uses.
- Once the use of a chemical substance is designated a significant new use, TSCA section 5(a)(1) requires companies to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use.
- The SNUN obligates EPA to review the notice, make an affirmative risk determination under TSCA section 5(a)(3); and, as appropriate, regulate the proposed activity before it occurs



2015 Proposed LCPFAC SNUR

- January 21, 2015 (LCPFAC SNUR #2; 80 FR 2885) – before the 2016 amendments to TSCA, EPA proposed to amend two existing SNURs on long-chain perfluoroalkyl carboxylate (LCPFAC) and perfluoroalkyl sulfonate (PFAS) chemical substances to ensure that such chemicals that have been phased out do not re-enter the marketplace without EPA review.
 - A complement to the PFOA Stewardship Program, where EPA encouraged companies to phase out PFOA and PFOA-related chemicals including potential PFOA precursors by the end of 2015, which they have done.
 - EPA proposed lifting the articles exemption over concerns that LCPFAC chemical substances that were voluntarily phased out would enter the U.S. market in imported articles.



2015 Proposed LCPFAC SNUR

- The proposed SNUR did four things:
 1. Proposed an amendment to a SNUR on LCPFAC chemical substances by designating as a significant new use manufacturing (including importing) or processing of a subset of LCPFAC chemical substances for any use that was no longer ongoing after December 31, 2015;
 2. Proposed an amendment to a SNUR for LCPFAC chemical substances by designating as a significant new use manufacturing (including importing) or processing of all other LCPFAC chemicals substances for any use that was no longer ongoing after January 21, 2015;
 3. Proposed an amendment to lift the exemption for persons who import a subset of LCPFAC chemical substances as part of articles; and
 4. Proposed an amendment to a SNUR for perfluoroalkyl sulfonate (PFAS) chemical substances that would lift the exemption for persons who import PFAS chemical substances as part of carpets.



2016 Lautenberg Amendments and Articles

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.



Lifting Articles Exemption for LCPFAC SNUR

- The amended TSCA requires the finding to be based on the reasonable potential for exposure through the article or categories of articles.
 - The 2015 proposed SNUR explained that the basis for making the exemption inapplicable to articles was the potential for exposure.
 - The 2015 proposed SNUR did not distinguish among categories of articles.
 - In order to better align with the 2016 amendments to TSCA, OCSPP AA determined, in the fall of 2016, to repropose lifting the article exemption for categories of articles.



Original Internal EPA Approach for Categories of Articles for Reproposal

Ex. 5 Deliberative Process (DP)



2019 Internal EPA Change to Categories of Articles for the Supplemental Proposal

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- **Ex. 5 Deliberative Process (DP)**



Supplemental Proposal to Meet the Requirements of New TSCA

- On February 20, 2020, EPA repoposed lifting the exemption for importers of the chemical in an article and added specific details on “reasonable potential for exposure” in order to be responsive to new TSCA.
- By lifting the article exemption for importation of articles with an LCPFAC-containing surface coating, EPA’s intent was to capture the importation of all articles containing LCPFAC chemical substances, rather than narrow the scope, while also meeting the requirements under TSCA section 5(a)(5).
- The supplemental proposal for the LCPFAC SNUR defined the category of articles containing the chemical subject to notification.
 - EPA defines as the **category of articles subject to this rule** “articles where certain LCPFAC chemical substances are part of **surface coating on articles**” based on the reasonable potential for exposure as shown through research on LCPFAC chemical substances.



Comments on Supplemental SNUR

- Definition of surface coating.
 - Final rule included no definition.
- Reasonable potential for exposure.
 - Final rule included no additional rationale.
- Safe harbor provision.
 - Final rule included no safe harbor provision.
- De minimus threshold.
 - Final rule included no de minimus threshold.



LCPFAC SNUR Final Rule

- July 27, 2020: Final Rule Published, taking final action on both the 2015 proposal and the 2020 supplemental proposal.
 - September 25, 2020: Effective Date
- The final rule did not include a regulatory definition of “surface coating” but did state that EPA would issue guidance within a reasonable timeframe of the final rule.



Surface Coating Guidance

- EPA issued draft guidance on December 16, 2020, with a 30-day public comment period that ended on January 15, 2021.
- On January 19, 2021, EPA issued a press release announcing the final guidance, which was posted to EPA's website. EPA did not respond to the eight public comments received during the comment period.
 - Commenters: 3M, Alliance for Automotive Innovation, Chemical Users Coalition, EDF, Retail Industry Leaders Association, SIA, Safer Chemicals Healthy Families et al., US Chamber of Commerce
- There were no changes made to the guidance between draft and final. The Federal Register notice announcing the guidance did not publish.



Options for Approach to the Guidance

Ex. 5 Deliberative Process (DP)



Summary

- New Chemicals Initiatives – follow-up discussion on options
- TSCA 8(a)(7) Rule – Ex. 5 Deliberative Process (DP)
 - Ex. 5 Deliberative Process (DP)**
- Ex. 5 Deliberative Process (DP)
 - Ex. 5 Deliberative Process (DP) ?
- LCPFAC SNUR Guidance – input on options?